

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 97F-0035]

**Ashland Chemical Co.; Withdrawal of Food Additive Petition****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 6A4490) proposing that the food additive regulations be amended to provide for the safe use of polypropylene glycol with a molecular weight of 1,200 to 3,000 as a defoaming agent in water for sliced potatoes.

**FOR FURTHER INFORMATION CONTACT:** Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3167.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of February 3, 1997 (62 FR 5011), FDA announced that a food additive petition (FAP 6A4490) had been filed by Ashland Chemical Co., One Drew Plaza,

Boonton, NJ 07005. The petition proposed to amend the food additive regulations in § 173.340 Defoaming agents (21 CFR 173.340) to provide for the safe use of polypropylene glycol with a molecular weight of 1,200 to 3,000 as a component of defoaming agents in wash water for sliced potatoes. Ashland Chemical Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: November 10, 1997.

**Laura M. Tarantino,***Acting Director, Office of Premarket Approval.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 97N-0479]

**Parke-Davis et al.; Withdrawal of Approval of 18 New Drug Applications, 7 Abbreviated Antibiotic Applications, and 53 Abbreviated New Drug Applications****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 18 new drug applications (NDA's), 7 abbreviated antibiotic applications (AADA's), and 53 abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**EFFECTIVE DATE:** December 29, 1997.

**FOR FURTHER INFORMATION CONTACT:** Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 6-413 .....	Super Anahist (neohetramine hydrochloride) .....	Parke-Davis, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 7-812 .....	Inhiston-APC (aspirin 3.5 grains (gr), caffeine 0.5 gr, phenacetin 2.5 gr, pheniramine maleate 10 milligrams (mg)).	Plough, Inc., P.O. Box 377, Memphis, TN 38151.
NDA 9-108 .....	Rauval (rauwolfia serpentina) Tablets .....	Glenwood-Palisades, P.O. Box 369, One New England Ave., Piscataway, NY 08855.
NDA 11-760 .....	Normacol (polycarbophil) Tablets .....	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NY 07033.
NDA 11-935 .....	Actifed (pseudoephedrine hydrochloride and triprolidine hydrochloride) Syrup.	Glaxo Wellcome Inc., Five Moore Dr., Research Triangle Park, NC 27709.
NDA 11-936 .....	Actifed (pseudoephedrine hydrochloride and triprolidine hydrochloride) Tablets.	Do.
NDA 11-950 .....	Tacaryl (methdilazine hydrochloride) Syrup, 4 mg/15 milliliters (mL).	Westwood-Squibb Pharmaceuticals, Inc., 100 Forest Ave., Buffalo, NY 14213-1091.
NDA 12-939 .....	Neutrapen (penicillinase injectable) .....	3M Pharmaceuticals, Bldg. 260-6A-22, 3M Center, St. Paul, MN 55144-1000.
NDA 15-438 .....	Meproamate Tablets USP, 200 mg, 400 mg .....	Zenith Goldline Pharmaceuticals, 140 Legrand Ave., Northvale, NJ 07647.
NDA 16-649 .....	Feminone Tablets .....	Pharmacia & Upjohn, 7000 Portage Rd., Kalamazoo, MI 49001-0199.
NDA 17-369 .....	Teldrin (chlorpheniramine maleate extended release) Spansules.	SmithKline Beecham Consumer Healthcare, 1500 Littleton Rd., Parsippany, NY 07054-3884.
NDA 17-906 .....	Lactulose Syrup .....	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
NDA 19-014 .....	Benylin Decongestant Cough Formula (diphenhydramine hydrochloride and pseudoephedrine hydrochloride).	Warner-Lambert Co., 170 Tabor Rd., Morris Plains, NJ 07950.
NDA 50-125 .....	Tablets Remanden-250 (Potassium Penicillin G with Probenecid).	Merck & Co., Inc., BLA-30, West Point, PA 19486.
NDA 50-137 .....	Cer-O-Cillin Sodium (crystalline sodium penicillin O).	Pharmacia & Upjohn